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SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER	
STROUD, JONATHAN R	

ART UNIT	PAPER NUMBER
3774	

NOTIFICATION DATE	DELIVERY MODE
07/09/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

sughrue@sughrue.com
PPROCESSING@SUGHRUE.COM
USPTO@SUGHRUE.COM

Office Action Summary	Application No.	Applicant(s)	
	10/523,618	COVELLI, BRUNO	
	Examiner	Art Unit	
	JONATHAN STROUD	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 17-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 17-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to applicant's arguments, filed 04/02/2010.

Response to Arguments

1. Applicant's arguments filed on 04/02/2010, concerning the 35 U.S.C. 103 rejections over Hoerstrup DE 19919625, have been fully considered but they are not persuasive.

2. Applicant first argues that the conclusions of the Office are based on an incorrect characterization of the cited references, an incorrect application of the references, and improper law.

Applicant posits that the Office based its obviousness rejection on the flaw technical assumption that because the frame and support can be made of PHA, they must have identical properties, and therefore, the frame and carrier are identical. This misconstrues the prior art. Because both elements can be made of PHA and other various materials, and the independent claim limitations read "biodegradable" and "poorly degradable" but do not further define those terms, the prior art Hoerstrup, which it should be noted again, appears to be substantially copied in this action, fully anticipates those broad limitations. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the chain length, production conditions, and density) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's argument that there would be no reason to combine Hoerstrup and Arru, and that they each do not teach the elements of the claims, Hoerstrup teaches a valve construction nearly identical to the majority of applicant's claim language. One of ordinary skill in the art would know that stented heart valves are a common practice in the art, as taught by Arru and other prior art references, and as such, stenting a degradable heart valve would be obvious to try, as suggested by Arru. Indeed, applicant's translated version of Hoerstrup on page 5, ll. 7-11 indicate that Hoerstrup anticipated the problem – "This tissue is however useful for implantation into a human heart only in a limited manner, since, due to its weak mechanical properties, it would not be suitable for the flow conditions at the place of implantation." Arru's more-rigid stent-and-biological tissue member solves this problem elegantly. Adding a more-rigid stenting member would be obvious to try.

Applicant is reminded that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims have been amended to replace the terms "non degradable or poorly degradable" frame construction to read "slowly" degradable frame construction. This limitation – slowly – does not appear in applicant's specification, and thus constitutes new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Rejections were made based on machine translations performed by Derwent, Google Translator, Babelfish and a standard Langenscheidt German-English English-German dictionary.

5. Claims 1-15 and 18-28 are rejected under 35 U.S.C. 103(a) as being anticipated by Hoerstrup DE 19919625, further in view of Arru 4,758,151. Text between " " is present claims language, text between [ ] is examiner's reasoning for applying prior art. Translations are reproduced in italics for clarity.

Hoerstrup anticipates the device as disclosed and claimed and as follows: "Providing a biodegradable support, colonizing the support with homologous fibroblasts and/or myofibroblasts cells to form a connective tissue matrix [abstract translation: *(i) colonizing a biodegradable carrier with homologous fibroblasts and/or myofibroblasts so as to give a connective tissue matrix*]; optionally colonizing the connective tissue matrix with endothelial cells [abstract translation: *(ii) colonizing the matrix with endothelial cells*]; and fixing of the matrix to a non-degradable or poorly degradable frame construction [the "carrier" as discussed above; furthermore, in the applicant's disclosure he sites that both the "non-degradable or poorly degradable frame construction" and "biodegradable support" can be constructed of PHA. Since both can be made of the same material, the use of the terms "biodegradable" and "poorly degradable" becomes non-limiting. Any part of the device can be considered either the frame or the carrier; the base of the device can be the frame, and the flaps the carrier, since they can be made of the same material.], before and/or after the fixing to the frame construction, the connective tissue matrix is introduced into a pulsatile flow chamber in which it can be exposed to increasing flow rates, and the flow rate is increased continuously or discontinuously [abstract translation*: iii) introducing the matrix into a pulsating flow chamber (e.g. in a bioreactor) where it is subjected to a (dis)continuous flow rate*].

Further, Hoerstrup teaches a material that degrades at least 8 days post colonization and is completely degraded within four to six weeks, p. 3, machine translation.

Hoerstrup fails to teach a poorly degradable frame construction where the frame does not degrade prior to a year after colonization.

Arru teaches the well-known practice of using pulsatile flow chambers to construct biodegradable supports and attach them to stents, as Hoerstrup does. Further, Arru teaches using a support structure, or stent, that is solid, such as a metal stent, col. 5 ll. 20-43. Still further, Arru teaches the well-known practice of providing such a construct with an expressly-named suture ring, col. 5 ll. 50-65, although it should be noted, any portion of Hoerstrup's design can be sutured, and is in ring shape, so hence can be named a "suture ring."

It would be obvious to one of ordinary skill in the art at the time of invention to modify Hoerstrup in view of Arru, in order to use a known stent support structure material, metal, which has superior stenting and support properties, with an easily-degradable connective tissue matrix, as is disclosed in Hoerstrup and Arru.

Furthermore, the addition of a "support" structure to Hoerstrup's design is obvious, since it can be made of the same material, and it has been held that the selection of a known material based on its suitability for its intended use supports a prima facie case for obviousness (Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945)], MPEP 2144.07) See Ionescu 4,441,216, Penny, III 4,816,029, and Rosen 4,345,340 for examples of stented heart valves.

Furthermore, the addition of a "suture ring" to Hoerstrup's design is obvious, since suture rings are well-known elements of the base product of the process – the

heart valve – that fill a well-known need. It would have been obvious to one of ordinary skill in the art to apply this known technique taught by Hoerstrup to the obvious design choice of a suture ring, which would yield predictable results.

The rearrangement of the steps in claim 2 does not change the process or product produced. It has been held that when the claimed and prior art products are identical in composition, a prima facie case of either anticipation or obviousness has been established. See In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01 [R-3].

6. Further, Hoerstrup teaches the device as discussed above where it is firmly connected the biodegradable support is a biodegradable polymer matrix or an acellular biological matrix, a polyglycolic acid (PGA), polylactic acid (PLA), polyhydroxyalkanoate (PHA), poly-4-hydroxybutyrate (P4HB) or a mixture of two or more of these polymers [[col. 2 ll. 65-68, col. 3 ll. 1-10], [" *...above said biodegradable carrier includes PHA, PGA, PLA and/or P4HB and combinations thereof*] the support has a polymer density of 40 to 120 mg/cm3 [col. 3 ll. 10-15], the support is a porous polymer having a pore size of 80 to 240 micrometers [col. 3 25-30] the fibers of the support have a diameter of 6 to 20 picometers [col. 3 ll. 20-25], the support is the connective tissue framework of an animal or human heart valve [col. 3 ll. 33-39], the step of colonization with fibroblasts or myofibroblasts is repeated 3 to 14 times [col. 4 ll. 29 - 48] approximately 10^5 to 6 x

10^8 fibroblasts or myofibroblasts of are employed per square centimeter of support/matrix [col. 4 ll. 10-20] the step of colonization with endothelial cells is repeated 3 to 14 times [col. 4 ll. 40-48], approximately 10^5 to 5 x 10^8 endothelial cells are employed per square centimeter of support/matrix [col. 4 ll. 40-48], the cells are human cells, which are autologous [col. 4 ll. 49-52], the frame construction is made of a biocompatible material [the carrier is constructed of the same material as the matrix ... i.e. PGA, PLA or PHA as described above], flow rates of 5 ml/min to 8,000 ml/min are established in the pulsatile flow chamber [col. 9 ll. 5-8: *range of 50-5,000 ml/min* anticipates the claimed range], the flow rate is increased over a period of 1 week to 12 weeks [col. 9 ll. 18-39, a 15-day increase falls within and anticipates the claimed range], the initial flow rate is 50 to 100 ml/min, the initial pulse frequency is 5 to 10 pulses/min, the flow rate is increased to 5,000 ml/min, the pulse frequency is increased to 180 pulses/min [col. 9 ll. 5-18], systemic pressures of 10 to 240 mm Hg are established in the pulsatile flow chamber [col. 9 ll. 40-44].

7. Claims 25-28 are anticipated by Hoestreup, since the heart valve claimed can be produced with the procedure as claimed above. See further col. 10 ll. 5-10 [collagen density of 43-55 %] and col. 10 ll. 9-15 [translation: *heart valve designed to withstand the flow conditions within the human heart*].

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hoerstrup in view of Rose 4,627,879. Hoerstrup teaches the invention as claimed and as discussed above, but fails to disclose the following claimed limitations taught by

Rose: using fibrin adhesive to adhere the support structure to the seeded matrix [col. 1 ll. 14-49]. It would have been obvious to one of ordinary skill in the art at the time of invention to modify Hoerstrup in view of Rose, in order to achieve a biocompatible, biodegradable seal between the matrix and carrier that preserves the qualities of porous grafts and the achieves hemostasis, as taught by Rose [col. 1 ll. 14-49].

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN STROUD whose telephone number is (571)270-3070. The examiner can normally be reached on 8-4, M-F

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Isabella whose telephone number is 571-272-4749. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan R Stroud/

Examiner, Art Unit 3774

/Thomas J Sweet/

Primary Examiner, Art Unit 3774